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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/767,638	01/29/2004	Paul S. Charifson	VPI/02-128 US	5416

27916 7590 09/15/2006

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EXAMINER	
BALLS, ROBERT J	

ART UNIT	PAPER NUMBER
1625	

DATE MAILED: 09/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/767,638	CHARIFSON ET AL.	
	Examiner	Art Unit	
	R. James Balls	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-31 are pending.

2. This application claims benefit of provisional application No. 60/443,917, filed on January 31, 2003.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim 18, drawn to compounds classified in class 546, subclass 193.

II. Claim 20 (excluding compounds encompassed by Claim 18), drawn to compounds classified in class 544, various subclasses depending on the species.

III. Claims 1-17, 19 and 21 (excluding compounds encompassed by Claims 18 and 20), drawn to compounds classified in 548, various subclasses depending on the species.

IV. Claim 22, drawn to compositions of Claim 21, additionally comprising an additional therapeutic agent selected from an antibiotic, an anti-inflammatory agent, a matrix metalloprotease inhibitor, a lipoxygenase inhibitor, a cytokine antagonist, an immunosuppressant, an anti-cancer agent, an anti-viral agent, a cytokine, a growth factor, an immunomodulator, a prostaglandin, an anti-vascular hyperproliferation compound or an agent which increases the susceptibility of bacterial organisms to antibiotics, classified in various classes and subclasses depending on the election of species. Applicants are further required to elect a single disclosed compound (of Claim 1) AND a single disclosed additional therapeutic agent useable together in a composition encompassed by Claim 22.

V. Claims 23-25 drawn to diagnostic methods classified class 435, various subclasses depending on species election. Applicants are required to elect a single disclosed species useable in the diagnostic methods of Claims 23-25 from which further restriction may apply.

VI. Claims 26-29 drawn to methods of decreasing bacterial quantity using compounds and compositions formula I classified in Class 514, subclass 256 and 315. Applicants are required to elect a single disclosed species useable in Claims 26-29 from which further restriction may apply.

VII. Claims 30-31 drawn to multiple active ingredient methods of using compounds and composition of formula I with an additional step of administering another therapeutic agent classified in class 513, various subclasses depending on the structure of the additional therapeutic agent. Applicants are required to elect a single disclosed compound (of Claim 1) AND a single disclosed therapeutic agent useable together for the instant method.

Claim 1-17, 19 and 21 link inventions I and II. The restriction requirement of the linked inventions is **subject to** the nonallowance of the linking claims, claims 1-17 and 19. Upon the indication of allowability of the linking claims, the restriction requirement as to the linked inventions **shall** be withdrawn and any claims depending from or otherwise requiring all the limitations of the allowable linking claims will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 **Claims that require all the limitations of an allowable linking claim** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicants are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-III have independent and distinct structures, which lack a substantial structural feature recognized in the art as being essential to the disclosed utility (see the groups different classification). A reference that anticipates any one of groups I-III would not render the other groups obvious. A search for one group is not coextensive with a search of any other group and it would be a tremendous burden to search all the groups without restriction. Should applicants traverse on the ground that the compounds are not patentably distinct, applicants should submit evidence or identify such evidence now or record showing compounds of groups I-III are obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in an obviousness rejection under 35 USC §103(a).

Invention IV is related to Inventions I-III in that the compositions of Invention IV contain a compound of Inventions I-III. However, Invention IV is patentably distinct from Inventions I-III due to the added element of an additional therapeutic agent. For instance, a reference that anticipates any one of groups I-III would not render invention IV obvious. Furthermore, a search Inventions I-III is not coextensive with a search of Invention IV and it would be a tremendous burden to search all the groups without restriction. Should applicants traverse on the ground that Inventions I-III are not patentably distinct from Invention IV, applicants should submit evidence or identify such evidence now or record showing compounds of groups I-III are obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds

one of the inventions unpatentable over the prior art, the evidence or admission may be used in an obviousness rejection under 35 USC §103(a).

Furthermore, Invention IV contains claims directed to the following patentably distinct species: antibiotic, an anti-inflammatory agent, a matrix metalloprotease inhibitor, a lipoxygenase inhibitor, a cytokine antagonist, an immunosuppressant, an anti-cancer agent, an anti-viral agent, a cytokine, a growth factor, an immunomodulator, a prostaglandin, an anti-vascular hyperproliferation compound or an agent which increases the susceptibility of bacterial organisms to antibiotics. The species are independent or distinct because they do not share a structure/activity relationship recognized in the art. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. A single disclosed species does not refer to one of the groups of agents included in claim 22 such as "an anti-inflammatory agent," but a specific anti-inflammatory compound disclosed in the specification as being useable in the claimed composition.

Inventions I-IV are related to Invention V-VII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the method of treating a bacterial infection can be practiced with another materially different product. For example, see Seng et al. (U.S. Patent No. 3,856,957), Claim 19.

Inventions V and VI are related, as they both use compounds and compositions of Inventions I-IV. The inventions are distinct because they have a materially different design, mode of operation, function, or effect and are not obvious variants of one antoher. See MPEP § 806.05(j). For example, a compound capable of treating a bacteria infection is not necessary capable of inhibiting gyrase activity. Ampicillin, for example, inhibits the third and final stage of bacterial cell wall synthesis, which ultimately leads to cell lysis. See http://en.wikipedia.org/wiki/Ampicillin. Furthermore, both methods are not obvious variants of one another. A reference that anticipates any one of groups V-VI would not render the other group obvious. A search for one group is not coextensive with a search of any other group and it would be a tremendous burden to search all the groups without restriction.

Invention VII is related to Inventions I-III in that the method of Invention VII uses a compound of Inventions I-III. Invention VII is related to Invention V in that they are both drawn to methods of treating disease. However, Invention VII is patentably distinct from preceding inventions due to the added step of an administering an additional therapeutic agent. For instance, a reference that anticipates any one of the preceding inventions would not render invention VII obvious due to the additional step. Furthermore, a search of the preceding inventions is not coextensive with a search of Invention VII and it would be a tremendous burden to search all the groups without restriction. Should applicants traverse on the ground that Invention VI is not patentably distinct from the preceding inventions, applicants should submit evidence or identify such evidence now or record or clearly admit on the record that this is the case. In

either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in an obviousness rejection under 35 USC §103(a). Applicant is required under 35 U.S.C. 121 to elect a single disclosed therapeutic agent for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. A single disclosed species does not refer to one of the groups of agents included in claim 22 such as "an anti-inflammatory agent," but a specific anti-inflammatory compound disclosed in the specification as being useable in the claimed method.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP §821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is *presented prior to* final rejection or allowance,

whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai; In re Brouwer and 35 U.S.C. §103(b)," 1184 O.G. 86 (March 26, 1996).

Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. *Applicants are reminded of propriety of process of use claims in consideration of the "reach-through" format, which is drawn to mechanistic, receptor binding or enzymatic functionality. Reach-through claims are considered lacking of descriptive and enabling support from the specification. Thus, rejoinable process of use claims are those with particular disease named with efficacy support from the specification for treating the particular disease.* **Failure to do so may result in a loss of the right to rejoinder**.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to R. James Balls whose telephone number is (571) 272-7997. The examiner can normally be reached on Mon - Fri 8:00am - 4:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tom McKenzie can be reached on (571) 272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

R. James Balls
September 7, 2006

Celia Chang
Primary Examiner
Art Unit 1625